

**REMARKS**

With the entry of the amendments presented above, claims 4-7, 9, 10, 12, 13, and 78-82 are now pending in this application.

Applicants note that, under “Disposition of Claims” on the Office Action summary, item 6 indicates that claims 1-7, 9, 10, 12, 13, and 72-82 are rejected. Applicants assume that this is a typographical error, and that claims 1, 2, and 3 are not under consideration, as they were cancelled in the amendment filed by facsimile on September 23, 2004. Applicants also note that, although the September 23, 2004 amendment appears to have been entered, the Office Action does not acknowledge the amendment. Clarification of these matters would be greatly appreciated.

**Specification**

The specification was objected to because of the presence of embedded hyperlinks. The specification has been amended to remove browser-executable code. Withdrawal of this objection is respectfully requested.

**Rejection under 35 U.S.C. § 112, second paragraph—indefinite**

Claim 12 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for reciting “A hybridoma that produces an antibody or fragment thereof...”

The claim has been amended to remove the words “or fragment thereof.” Applicants submit that the claim as amended is now definite, and respectfully request removal of this rejection.

**Rejections under 35 U.S.C. § 102(e)**

Claims 4-7, 9-10, 12-13 and 78-82 were rejected under 35 U.S.C. § 102(e) as being anticipated by Tang et al. (WO 01/53312).

This rejection is respectfully traversed. The Tang reference apparently discloses 3,572 nucleic acid sequences (SEQ ID NO:1-1786 and SEQ ID NO:3573-5358) and their amino acid

translations, for a total of 7,144 nucleic acid and protein sequences. Exhibit A (Result 3, accession number AAM40043) accompanying the Office Action indicates that the sequence is disclosed in Example 4 of Tang. A review of Example 4 at page 98 to page 99 of Tang does not indicate any discussion of Tang SEQ ID NO:3188 at all, nor a specific discussion of what appears to be its corresponding nucleic acid, Tang SEQ ID NO:1402 (see page 293 of WO 01/53312). Thus it appears that the only actual disclosure of the sequence is buried in the sequence listing for the application. Further, the Tang sequence only discloses 190 residues of the 205 amino acids of Applicants' sequence, or less than 93%. The number "3188" appears to be mentioned only once in the printed specification, at page 293.

The application does not appear to discuss any specific utility for Tang SEQ ID NO:3188. The application appears to simply present a huge list of nucleic acid sequences, together with their putative amino acid sequences. The application also speculates on several uses for the sequences. Apparently the inventors were just hoping that *at least one* of the thousands of sequences listed will have *at least one* of the uses listed:

The present invention relates to a collection or library of **at least one novel nucleic acid sequence** assembled from expressed sequence tags (ESTs) isolated mainly by sequencing by hybridization (SBH), and in some cases, sequences obtained from one or more public databases.  
(WO 01/53312, page 2, lines 1-3; emphasis added)

The presently pending claims are directed to antibodies and associated technologies (antibody fragments, antibody conjugates, hybridomas, etc.) against a specific defined sequence, SEQ ID NO:3 of the instant application. In contrast, the Tang application simply describes a method for making antibodies, with apparently no description whatsoever of what those antibodies should be raised against. Apart from the mention of Tang SEQ ID NO:1787 (page 74, line 22 of WO 01/53312), there does not appear to be any guidance to prepare antibodies against any specific sequence in the application. Tang merely states that "also included in the invention are antibodies to proteins, or fragments of proteins of the invention" (page 74, lines 5-6 of WO 01/53312), leaving the skilled artisan with nothing more than an invitation to experiment on the thousands of sequences. Indeed, Tang does not even offer the skilled artisan any indication that Tang SEQ ID

NO:3188 is actually expressed in cells or tissues. It could well be that many, perhaps most, of the amino acid sequences in Tang are simply bioinformatic artifacts, translations of nucleic acids that are never actually expressed *in vivo*.

Applicants are aware that the utility standards of 35 U.S.C. § 101 and 35 U.S.C. § 112 for the patent application being cited are distinct from the standard of 35 U.S.C. § 102(e). However, 35 U.S.C. § 102(e) does require that the invention be described in the prior art reference. Given the complete lack of guidance as to exactly what Tang's "invention" is, it cannot be said that Tang describes anything beyond a laundry list of sequences and the rather forlorn hope that *one* of them, *any* of them, will turn out to be good for *something*. Thus Tang cannot be said to describe antibodies (or fragments thereof, etc.) to Applicants' SEQ ID NO:3.

Accordingly, Applicants respectfully request withdrawal of this rejection.

Claims 4-7, 9-10, 12-13 and 78-79 were rejected under 35 U.S.C. § 102(e) as being anticipated by Edwards et al. (U.S. 6,639,063).

This rejection is respectfully traversed. The arguments above regarding Tang apply with even more force to Edwards. According to the USPTO records at <http://seqdata.uspto.gov/sequence.html?DocID=06639063B1>, Edwards discloses 19,335 sequences. The sequence listing has not been examined to determine how many of these are protein sequences and how many are nucleotide sequences, but it seems likely that Edwards also discloses thousands of protein sequences. A search of the full text of U.S. 6,639,063 indicates that the cited sequence, Edwards SEQ ID NO:4959, is not specifically mentioned in the specification. Thus, as in the Tang reference, the only disclosure of the sequence in Edwards appears in the sequence listing (and it should be noted that this sequence overlaps only 117 residues, or about 57.1%, of the 205 amino acids of Applicants' SEQ ID NO:3). There is no disclosure of antibodies (or antibody-related technology) against Applicants' SEQ ID NO:3, as the claims of the instant application recite. In Edwards (as in Tang, *supra*) the skilled artisan is provided with nothing besides a mere invitation to extensive experimentation.

Accordingly, Applicants respectfully request withdrawal of this rejection.

Rejection under 35 U.S.C. § 103(a)

Claims 4-7, 9-10, 12-13 and 78-82 were rejected under 35 U.S.C. § 103(a) as unpatentable over Edwards et al. (U.S. 6,639,063) in view of Thorpe et al. (U.S. 6,342,219).

This rejection is respectfully traversed. Again, as above, Edwards fails to disclose antibodies (or antibody fragments, hybridomas producing antibodies, etc.) to the specific protein of the instant claims. There is no motivation in Edwards alone to make antibodies to each of the thousands of sequences described, and the addition of Thorpe does not supply any guidance to select one specific sequence out of the myriad of sequences in Edwards. Thus, the combination of Edwards with Thorpe is insufficient to render the claims obvious under 35 U.S.C. § 103(a).

Accordingly, Applicants respectfully request withdrawal of this rejection.

**CONCLUSION**

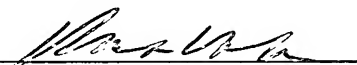
Applicants submit that in view of the claims as currently amended, all outstanding objections and rejections (objection to the specification, rejection under 35 U.S.C. § 112 second paragraph, rejections under 35 U.S.C. § 102(e), rejection under 35 U.S.C. § 103(a)) have been addressed. Reconsideration and allowance of the claims is earnestly solicited.

If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 511582003420. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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